

IN THE CLAIMS:

1-38. (Cancelled)

39. (Currently Amended) An orthopedic A unilaterally-hinged osteoarthritis knee brace for controlling movement of a wearer's knee comprising:

a rigid thigh engaging member;

a rigid calf engaging member; and

a unilateral lateral hinge lateral to the wearer's knee, connecting said thigh engaging member to said calf engaging member;

wherein said thigh engaging member and said calf engaging member form rigid connections to said lateral hinge,

wherein said lateral hinge further comprises a plurality of parallel, concentric, spherical shells and a plurality of cam follower pins and a plurality of cam slots distributed among said shells, wherein said plurality of cam follower pins engage said plurality of cam slots to rotatably engage said shells, and wherein a side of each of said cam follower pins is shaped to track a path parallel to a side of each of said cam slots in which said pin is engaged,

wherein said lateral hinge has a first variable axis of rotation and comprises:

a first shell, a second shell, and a third shell in the shape of a segment of a sphere, said first and third shells being concentric and fastened parallel to each other to form a first opening, said first and third shells being fastened to a lateral portion of either said thigh engaging member or said calf engaging member, said second shell having a first end designed to be inserted into said first opening and a second end fastened to a lateral portion of the other of said said thigh engaging member or calf engaging member, said first and third shells rotatably engaged to said second shell by said plurality of cam follower pins and said plurality of cam slots;

wherein said lateral hinge further comprises:

a first cam follower pin and second cam follower pin distributed among said shells and extending inside said first opening, said first pin located on said second shell and said second pin located on said third shell, and a first cam slot and second cam slot distributed among said shells to receive said first and second pins, respectively, said first

shell comprising said first cam slot and said second shell comprising said second cam slot,

whereby, in use, when the wearer's leg is extended, said first variable axis of rotation is in alignment with the wearer's condyles, and wherein said knee brace prescribes asymmetric three-dimensional anatomic motion in six degrees of freedom by actively prescribing flexion and extension, abduction and adduction, internal/external rotation, anterior/posterior translation, medial/lateral translation, and proximal/distal translation between a femur and a tibia of the wearer's leg.

a unilateral hinge selected from a hinge lateral to the wearer's knee connecting said thigh engaging member to said calf engaging member, or a hinge medial to the wearer's knee connecting said thigh engaging member to said calf engaging member, wherein said knee brace prescribes asymmetric three-dimensional anatomic motion in six degrees of freedom between a femur and a tibia during flexion and extension of a wearer's leg.

40-43. (Cancelled).

44. (Original) The orthopedic knee brace of claim 39, further comprising:
an upper lateral hinge linkage forming a connection between said thigh engaging member and said lateral hinge; and

a lower lateral hinge linkage forming a connection between said calf engaging member and said lateral hinge.

45-46. (Cancelled)

47. (Currently Amended) The orthopedic knee brace of claim 39, wherein said side of said cam follower pin at a point closest to said cam slot is parallel to said side of said cam slot the sides of said first and second cam follower pins at points closest to said first and second cam slots, respectively, are parallel to the sides of said first and second cam slots, respectively, throughout the range of motion from flexion to extension of said knee brace.

48. (Currently Amended) The orthopedic knee brace of claim 47, wherein said side of said cam follower pin at the point closest to said cam slot forms an angle said side of said cam follower pin at a point closest to said cam slot is parallel to said side of said cam slot the sides of said first and second cam follower pins at points closest to said

first and second cam slots, respectively, are parallel to the sides of said first and second cam slots, respectively, form angles to a radial axis of said spherical shell.

49. (Currently Amended) The orthopedic knee brace of claim 48, wherein said angle is angles are between approximately 0 and 45 degrees.

50. (Currently Amended) The orthopedic knee brace of claim [[46]]39, further comprising an extension stop member attached to said hinge to limit flexion and extension of the tibia relative to the femur of the wearer's leg.

51. (Previously Presented) The orthopedic knee brace of claim 39 further comprising:

attachment means on said thigh engaging member to attach said thigh engaging member to a wearer's thigh;

attachment means on said calf engaging member to attach said calf engaging member to a wearer's calf.

52. (Previously Presented) The orthopedic knee brace of claim 39, further comprising a dynamic force strap attaching said thigh engaging member and said calf engaging member to the wearer's leg.

53. (Cancelled)

54. (Previously Presented) The orthopedic knee brace of claim 39, wherein said hinge has a concave surface facing the knee.

55. (New) The orthopedic knee brace of claim 50, wherein said extension stop member limits extension of the tibia relative to the femur to a minimum flexion angle between approximately 0 degrees and approximately 20 degrees.

56. (New) The orthopedic knee brace of claim 39, wherein each of said thigh engaging member and said calf engaging member has a unitary construction.

57. (New) The orthopedic knee brace of claim 56, wherein said unitary construction is molded construction.

58. (New) The orthopedic knee brace of claim 56, wherein said unitary construction is laminated single body construction.

59. (New) The orthopedic knee brace of claim 39, wherein said first and third shells further comprise a lateral inside shell and a lateral outside shell, said lateral inside shell having a first extension rigidly fastened to said lateral portion of said thigh engaging

member, said lateral outside shell having a second extension rigidly fastened to said lateral portion of said thigh engaging member, said second shell having a third extension rigidly fastened to said lateral portion of said calf engaging member.

60. (New) The orthopedic knee brace of claim 39, wherein said first, second and third shells have a spherical surface defining a first radius.

61. (New) The orthopedic knee brace of claim 60, wherein said first radius is in a range from approximately 2.5 inches to 3.5 inches.

62. (New) The orthopedic knee brace of claim 60, wherein said first radius is in a range from approximately 1.5 inches to 2.5 inches.

63. (New) The orthopedic knee brace of claim 39 wherein said substantially rigid thigh engaging member and said substantially rigid calf engaging member are composed of a reinforced fiber filled thermoplastic resin.

64. (New) The orthopedic knee brace of claim 39 wherein said lateral hinge is composed of a metal.

65. (New) The orthopedic knee brace of claim 64, wherein said lateral hinge is composed of aluminum.

66. (New) The orthopedic knee brace of claim 39 wherein said substantially rigid thigh engaging member and said substantially rigid calf engaging member are composed of a composite of reinforced fiber filled thermoplastic resin and metal.

67. (New) The orthopedic knee brace of claim 39 wherein said lateral hinge is composed of a composite of reinforced fiber filled thermoplastic resin and metal.

68. (New) A unilaterally-hinged osteoarthritis knee brace comprising:
a rigid thigh engaging member;
a rigid calf engaging member; and
a unilateral medial hinge medial to the wearer's knee, connecting said thigh engaging member to said calf engaging member,

wherein said thigh engaging member and said calf engaging member form rigid connections to said medial hinge,

wherein said medial hinge further comprises a plurality of parallel, concentric, spherical shells and a plurality of cam follower pins and a plurality of cam slots distributed among said shells, wherein said plurality of cam follower pins engage said

plurality of cam slots to rotatably engage said shells, and wherein a side of each of said cam follower pins is shaped to track a path parallel to a side of each of said cam slots in which said pin is engaged,

wherein said medial hinge has a second variable axis of rotation and comprises:

a fourth shell, a fifth shell, and a sixth shell in the shape of a segment of a sphere, said fourth and sixth shells being concentric and fastened parallel to each other to form a second opening, said fourth and sixth shells being fastened to a medial portion of either of said thigh engaging member or calf engaging member, said fifth shell having a first end designed to be inserted into said second opening and a second end fastened to the a medial portion of the other of said thigh engaging member or calf engaging member, said fourth and sixth shells rotatably engaged to said fifth shell by said plurality of cam follower pins and said plurality of cam slots;

and wherein said medial hinge further comprises:

a third cam follower pin and a fourth cam follower pin distributed among said shells and extending inside said second opening, said third pin located on said fifth shell and said fourth pin located on said sixth shell, and a third cam slot and fourth cam slot distributed among said shells to receive said third and fourth pins, respectively, said fourth shell comprising said third slot and said fifth shell comprising said fourth slot,

whereby, in use, when the wearer's leg is extended, said second variable axis of rotation is in alignment with the wearer's condyles, and wherein said knee brace prescribes asymmetric three-dimensional anatomic motion in six degrees of freedom by actively prescribing flexion and extension, abduction and adduction, internal/external rotation, anterior/posterior translation, medial/lateral translation, and proximal/distal translation between a femur and a tibia of the wearer's leg.

69. (New) The orthopedic knee brace of claim 68, further comprising:

an upper medial hinge linkage forming a connection between said thigh engaging member and said medial hinge; and

a lower medial hinge linkage forming a connection between said calf engaging member and said medial hinge.

70. (New) The orthopedic knee brace of claim 68 wherein the sides of said first and second cam follower pins at points closest to said first and second cam slots,

respectively, are parallel to the sides of said first and second cam slots, respectively, throughout the range of motion from flexion to extension of said knee brace.

71. (New) The orthopedic knee brace of claim 70, wherein the sides of said first and second cam follower pins at points closest to said first and second cam slots, respectively, are parallel to the sides of said first and second cam slots, respectively, form angles to a radial axis of said spherical shell.

72. (New) The orthopedic knee brace of claim 71, wherein said angles are between approximately 0 and 45 degrees.

73. (New) The orthopedic knee brace of claim 68, further comprising an extension stop member attached to said hinge to limit flexion and extension of the tibia relative to the femur of the wearer's leg.

74. (New) The orthopedic knee brace of claim 68 further comprising:
attachment means on said thigh engaging member to attach said thigh engaging member to a wearer's thigh;

attachment means on said calf engaging member to attach said calf engaging member to a wearer's calf.

75. (New) The orthopedic knee brace of claim 68, further comprising a dynamic force strap attaching said thigh engaging member and said calf engaging member to the wearer's leg.

76. (New) The orthopedic knee brace of claim 68, wherein said hinge has a concave surface facing the knee.

77. (New) The orthopedic knee brace of claim 73, wherein said extension stop member limits extension of the tibia relative to the femur to a minimum flexion angle between approximately 0 degrees and approximately 20 degrees.

78. (New) The orthopedic knee brace of claim 68, wherein each of said thigh engaging member and said calf engaging member has a unitary construction.

79. (New) The orthopedic knee brace of claim 78, wherein said unitary construction is molded construction.

80. (New) The orthopedic knee brace of claim 78, wherein said unitary construction is laminated single body construction.

81. (New) The orthopedic knee brace of claim 68, wherein said fourth and sixth shells further comprise a medial inside shell and a medial outside shell, said medial inside shell having a fourth extension rigidly fastened to said medial portion of said thigh engaging member, said medial outside shell having a fifth extension rigidly fastened to said medial portion of said thigh engaging member, said fifth shell having a sixth extension rigidly fastened to said medial portion of said calf engaging member.

82. (New) The orthopedic knee brace of claim 68, wherein said fourth, fifth, and sixth shells have a spherical surface defining a second radius.

83. (New) The orthopedic knee brace of claim 82, wherein said second radius is in a range from approximately 2.5 inches to 3.5 inches.

84. (New) The orthopedic knee brace of claim 82, wherein said second radius is in a range from approximately 1.5 inches to 2.5 inches.

85. (New) The orthopedic knee brace of claim 68 wherein said substantially rigid thigh engaging member and said substantially rigid calf engaging member are composed of a reinforced fiber filled thermoplastic resin.

86. (New) The orthopedic knee brace of claim 68 wherein said medial hinge is composed of a metal.

87. (New) The orthopedic knee brace of claim 86, wherein said medial hinge is composed of aluminum.

88. (New) The orthopedic knee brace of claim 68 wherein said substantially rigid thigh engaging member and said substantially rigid calf engaging member are composed of a composite of reinforced fiber filled thermoplastic resin and metal.

89. (New) The orthopedic knee brace of claim 68 wherein said medial hinge is composed of a composite of reinforced fiber filled thermoplastic resin and metal.